DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 31, 2014

Medtronic Advanced Energy
Mr. Deep Pal
Principal Regulatory Affairs Specialist
180 International Drive
Portsmouth, New Hampshire 03801

Re: K143175
Trade/Device Name: AEx Generator
PlasmaBlade T
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 4, 2014
Received: November 5, 2014

Dear Mr. Pal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 8: INDICATIONS FOR USE STATEMENT

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143175

Device Name

AEx Generator
PlasmaBlade T

Indications for Use *(Describe)*

AEx Generator:

The AEx Generator is a radio frequency (RF) electrosurgical generator capable of simultaneously powering specified monopolar and bipolar electrosurgical instruments. It is intended to be used for delivery of RF energy to instruments indicated for cutting and coagulation of soft tissue and for delivery of RF energy concurrent with saline to instruments indicated for hemostatic sealing and coagulation of soft tissue and bone. It is intended for, but not limited to, General, Plastic and Reconstructive (including but not limited to skin incisions and development of skin flaps), ENT, Gynecologic, Orthopaedic, Arthroscopic, Spinal and Neurological, Thoracic, and Open Abdominal Surgery procedures. The device is not intended for contraceptive tubal coagulation (Permanent Female Sterilization).

PlasmaBlade T:

The PlasmaBlade T is a monopolar, single use, sterile, disposable device intended for use with the AEX Generator. The device delivers RF energy concurrent with saline for hemostatic sealing and coagulation of soft tissue and bone and RF energy for cutting and coagulation of soft tissue. It is intended for, but not limited to, General, Plastic and Reconstructive (including but not limited to skin incisions and development of skin flaps), ENT, Gynecologic, Orthopaedic, Arthroscopic, Spinal, Thoracic, and Open abdominal surgery procedures. The device is not intended for contraceptive tubal coagulation (permanent female sterilization).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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SECTION 9: 510(k) SUMMARY

This summary of substaintial equivalence is submitted in accordance with the requirements of 21CFR807.92.

9.1 DATE PREPARED
November 3, 2014

9.2 NAME AND ADDRESS OF THE 510(k) OWNER
Medtronic Advanced Energy
180 International Drive
Portsmouth, NH 03801

9.3 CONTACT PERSON
Deep Pal
Principal Regulatory Affairs Specialist
Telephone: 817.788.6685
Facsimile: 817.788.6222
E-Mail: deep.pal@medtronic.com

9.4 PROPRIETARY NAME OF THE PROPOSED DEVICES
AEX Generator *(Device Catalog Number: 40-405-1)*; and
PlasmaBlade T Handpiece *(Device Catalog Number: 27-101-1)*

9.5 COMMON/USUAL NAME
Electrosurgical Device and Accessories

9.6 DEVICE CLASSIFICATION NAME
Electrosurgical Cutting and Coagulation Device and Accessories
(21 CFR 878.4400, Product Code GEI, Class II)

9.7 PREDICATE DEVICE IDENTIFICATION
The devices that are within the scope of this 510(k) Submission, the proposed AEX Generator and PlasmaBlade T Handpiece devices, are substantially equivalent to the following predicates:

PROPOSED DEVICE		CLAIMING SUBSTANTIAL EQUIVALNCE TO	
AEX	**PlasmaBlade T**	**PREDICATE DEVICE**	**510(k) NUMBER**
✓	N/A	Aquamantys System - Aquamantys Generator and Aquamantys Handpieces	K052859
✓	✓	PEAK Surgery System - PULSAR Generator and PlasmaBlade Handpieces	K082786
N/A	✓	Aquamantys SBS 5.0 Handpiece	K111732, K132974

Table 2: Predicate device claiming equivalence to

9.8 DEVICE DESCRIPTION

Currently included as part of the system in this 510(k) submission are the AEX Generator, and the PlasmaBlade T Handpiece which is a one hand-held disposable, sterile, single use disposable electrosurgical device that is compatible only with the AEX Generator.

The information on the previously cleared hand-held disposable electrosurgical handpieces that are compatible with the AEX Generator is provided in section 9.8.3.

9.8.1 AEX GENERATOR

In one compact generator, the proposed AEX system provides the functional capabilities available in two separate previously marketed generators: the Medtronic Pulsar Generator (Previously cleared under K082786) and the Aquamantys Generator (Previously cleared under K052859). The AEX Generator applies similar fundamental technologies and methods of operation as the predicate Generators, delivering bipolar and monopolar RF energy for resection and coagulation of soft tissue, and RF based hemostatic sealing concurrent with saline delivery for hemostatic and coagulation sealing of soft tissue and bone at the operative site.

The AEX Generator is a line powered, electrosurgical generator with monopolar and bipolar RF that is intended for use only with specific compatible Medtronic electrosurgical Handpieces; the AEX compatible Handpieces are identified in Section 9.8.3. The AEX Generator is a shelf-top unit consisting of a plastic, metal housing and a front LCD control panel. The Generator has a peristaltic pump outside the generator's housing, which is capable of transferring saline through the disposable accessory device concurrent with the generator's provision of RF energy. The LCD control panel is a touchscreen and serves as the user interface for power and saline settings. The AEX Generator has three-pin and seven-pin receptacles in its front panel that provides for the monopolar PlasmaBlade and bipolar Aquamantys disposable Handpieces connection to the Generator's RF power.

The proposed PlasmaBlade T Handpiece connection to the AEX Generator pump is configured to interface with the AEX Generator peristaltic pump. The AEX Generator accepts designated, commercially available, split-pad and single foil patient return electrode pads (neutral electrodes), non-REM neutral electrodes for monopolar applications <= 50 Watts, and provides monitoring of the patient return circuit for safety purposes.

9.8.2 PLASMABLADE T HANDPIECE

The proposed single-use disposable accessory device, the PlasmaBlade T monopolar handpiece, provides the hemostatic capabilities of the Aquamantys SBS 5.0 Handpiece (Cleared under K111732, K132974) and the cutting and coagulative capabilities of the PEAK PlasmaBlade 4.0 (Previously cleared under K082786).

The proposed PlasmaBlade T Handpiece device is a monopolar, single use, disposable devices and is provided sterile. The devices are not intended for reuse or resterilization. The PlasmaBlade T handpieces consists of an enamel coated insulated blade electrode, an insulated telescoping shaft, handle with three integrated controls, and a co-extruded

cable assembly to provide both power and saline. The seven-pin electrical connector is designed to be plugged into the proposed AEx Generator.

The proposed PlasmaBlade T Handpiece is a disposable device, that when connected to the AEX Generator, uses monopolar RF energy for the resection and coagulation of soft tissue and bone. The proposed PlasmaBlade T Handpiece device shares similar handpiece designand tip configuration as its predicate device, the PlasmaBlade 4.0 Monopolar Handpiece (Cleared under K082786).

In addition to the monopolar cutting and coagulation capabilities the propsoed PlasmaBlade T Handpiece device also uses monopolar RF energy concurrent with saline delivery to provide a broader coagulative effect; similar to the predicate Aquamantys SBS 5.0 Handpiece (Cleared under K111732, K132974), this result is trademarked as Transcollation® Technology by Medtronic. The proposed PlasmaBlade T Handpiece device also has a pump header tubing segment and saline bag spike tubing allowing the user to manually connect the device to saline source in the OR as well as the AEX Generator's peristaltic pump. This ensures the device is connected for saline delivery at the same time as the device is connected electrically to the proposed AEX Generator.

9.8.3 ELECTROSURGICAL HANDPIECE DEVICES COMPATIBLE WITH THE AEX GENERATOR

The proposed AEX Generator will power the following proposed and the previously cleared hand-held disposable electrosurgical handpieces currently marketed by Medtronic:

HANDPIECE			GENERATOR COMPATIBILITY		
510(k) NUMBER	**NAME**	**TYPE**	**AEX[1]**	**PULSAR[3]**	**AQM[3]**
Subject of this submission	*PlasmaBlade T[1]*	*Monopolar*	✓	-	-
K082786	PlasmaBlade 4.0[2]	Monopolar	✓	✓	-
K082786	PlasmaBlade Needle	Monopolar	✓	✓	-
K083415	PlasmaBlade Tonsil	Monopolar	✓	✓	-
K083415	PlasmaBlade TnA	Monopolar	✓	✓	-
K083415	PlasmaBlade Adenoid TIP	Monopolar	✓	✓	-
K093695	PlasmaBlade 3.0S	Monopolar	✓	✓	-
K102709	PlasmaBlade PLUS	Monopolar	✓	✓	-
K103775	PlasmaBlade Suction Coagulator	Monopolar	✓	✓	-
K052859	Aquamantys 6.0	Bipolar	✓	-	✓
K052859, K111285, K132974	Aquamantys 2.3	Bipolar	✓	-	✓
K063639, K132974	Aquamantys EVS 4.0	Bipolar	✓	-	✓
K063639, K132974	Aquamantys Mini EVS 3.4	Bipolar	✓	-	✓
K073495	Aquamantys MBS with Light	Bipolar	✓	-	✓
K101057	Aquamantys 9.5XL	Bipolar	✓	-	✓
K111732, K132974	Aquamantys SBS 5.0[2]	Bipolar	✓	-	✓
K123201	Aquamantys Endo DBS 8.7	Bipolar	✓	-	✓

[1]Subject of this submission.
[2]Predicates for the proposed PlasmaBlade T Handpiece.
[3]Predicates for the proposed AEX Generator: AQM (K052859), Pulsar Generator (K082786)

Table 3: AEX Generator compatible Handpieces

9.9 INDICATIONS FOR USE

9.9.1 AEX GENERATOR

The AEX Generator is a radio frequency (RF) electrosurgical generator capable of simultaneously powering specified monopolar and bipolar electrosurgical instruments. It is intended to be used for delivery of RF energy to instruments indicated for cutting and coagulation of soft tissue and for delivery of RF energy concurrent with saline to instruments indicated for hemostatic sealing and coagulation of soft tissue and bone. It is intended for, but not limited to, General, Plastic and Reconstructive (including but not limited to skin incisions and development of skin flaps), ENT, Gynecologic, Orthopaedic, Arthroscopic, Spinal and Neurological, Thoracic, and Open Abdominal Surgery procedures. The device is not intended for contraceptive tubal coagulation (Permanent Female Sterilization).

9.9.2 PLASMABLADE T HANDPIECE

The PlasmaBlade T is a monopolar, single use, sterile, disposable device intended for use with the AEX Generator. The device delivers RF energy concurrent with saline for hemostatic sealing and coagulation of soft tissue and bone and RF energy for cutting and coagulation of soft tissue. It is intended for, but not limited to, General, Plastic and Reconstructive (including but not limited to skin incisions and development of skin flaps), ENT, Gynecologic, Orthopaedic, Arthroscopic, Spinal, Thoracic, and Open abdominal surgery procedures. The device is not intended for contraceptive tubal coagulation (permanent female sterilization).

9.10 SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The predicates and the proposed AEX generator and Plasmablade T are both intended for RF based resection and coagulation of soft tissue, and RF based hemostatic sealing concurrent with saline delivery for hemostatic sealing and coagulation of soft tissue and bone during various surgical procedures. The proposed devices share the same operational characteristics as the predicate platforms, comprised of a radio-frequency generator which supplies RF power to disposable electrode devices for electrosurgical procedures.

9.10.1 AEX GENERATOR

The AEx Generator applies the same fundamental technology as the predicate Aquamantys Generator (Previously cleared under K052859) and the Pulsar Generator (Previously cleared under K082786) in that it delivers bipolar and monpolar RF energy for resection and coagulation of soft tissue and bone, and RF based hemostatic sealing concurrent with saline delivery at the operative site.

9.10.2 PLASMABLADE T HANDPIECE

The proposed single-use disposable accessory device, the PlasmaBlade T monopolar handpiece, provides the hemostatic capabilities of the Aquamantys SBS 5.0 Handpiece (Cleared under K111732, K132974) and the cutting and coagulative capabilities of the PEAK PlasmaBlade 4.0 (Previously cleared under K082786).

Medtronic

9.11 SUMMARY OF NON-CLINICAL TESTING

9.11.1 THERMAL EFFECTS ON TISSUE

The representative legally marketed Aquamantys and the PlasmaBlade Handpieces with the proposed AEX Generator were evaluated side by side against the predicate Aquamantys Generator (Cleared under K052859) and Pulsar Generator (Cleared under K082786) devices, in the in-vivo, ex-vivo animal (porcine) studies.

Thermal Effects on Tissue of the proposed PlasmBlade T Handpiece with the proposed AEX Generator was also evaluated side by side against the performance of the predicate Handpieces with the AEX Generator, in the in-vivo, ex-vivo animal (porcine) studies.

These studies demonstrated that the comparisons of the data show no clinically significant difference where the proposed AEX Generator exhibited a comparable zone of thermal damage as the predicate Aquamantys and Pulsar Generators. Furthermore, the proposed PlasmaBlade T tip assembly and performance exhibited a comparable zone of thermal damage as the predicate Aquamantys SBS 5.0 (Previously cleared under K111732, K132974) and PlasmaBade 4.0 (Previously cleared under K082786) Handpieces.

9.11.2 SOFTWARE VERIFICATION

The software development and testing was executed in compliance to the following FDA Recognized Consensus Standard:

RECOGNITION NUMBER	STANDARD	TITLE OF STANDARD
13-8	IEC 62304 Edition 1: 2006	Medical Device Software - Software Life Cycle Processes

Table 4: Software Verification

9.11.3 ELECTOMAGNETIC COMPATIBILITY

The proposed AEX Generator was tested in compliance to the following FDA Recognized Consensus Standards:

RECOGNITION NUMBER	STANDARD	TITLE OF STANDARD
19-1	IEC 60601-1-2 Edition 3: 2007-03	Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
6-228	IEC 60601-2-2 Edition 5.0 2009-02	Medical electrical equipment Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

Table 5: Electromagnetic Compatibility

9.11.4 ELECTRICAL SAFETY

The proposed AEX Generator and the PlasmaBlade T Handpiece devices were tested in compliance to the following FDA Recognized Consensus Standards:

RECOGNITION NUMBER	STANDARD	TITLE OF STANDARD
19-4	IEC 60601-1:2005 3rd Edition And A1:2012	Medical electrical equipment-Part 1: General requirements for safety and Essential Performance
6-228	IEC 60601-2-2 Edition 5.0 2009-02	Medical electrical equipment Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

Table 6: Electrical Safety of the AEX Generator and the PlasmaBlade T Handpiece

9.11.5 BENCH-TOP PERFORMANCE TESTING

General performance verification testing of the proposed AEX Generator and the PlasmaBlade T devices were also performed to verify the peformance and output characteristics.

9.12 CONCLUSION

Based on the various testing performed, including the ex-vivo, in-vivo animal study, sofware verification testing, electrical safety and electromagnetic compatibility testing, it can be concluded that the proposed devices do not introduce considerations for safety and efficacy different from the considerations of their predicate devices. The similar indications for use, technology and performance characteristics of the proposed AEX Generator and the PlasmaBlade T Handpiece are assessed to be substantially equivalent to the predicate devices.